NONIN

MODEL
9571

GO2™ LED

User Guide

Table of Contents

Introduction 1

Contents of Package 1

Symbols 2

Intended Use 4

Installing the Battery 8

*Applying the **GO_2 LED** Model 9571 to Your Finger* 10

Activating the Device and Verifying Operation 12

Reading Your Results 13

Care and Maintenance 15

Specifications 20

Equipment Response Time 23

Testing Summary 24

SpO_2 Accuracy Testing 24

Pulse Rate Motion Testing 24

Low Perfusion Testing 24

Warranty 25

ENGLISH

Introduction

Thank you for buying the ***GO$_2$LED*** Model 9571 Fingertip Pulse Oximeter. This small, portable device will give you important information about your oxygen saturation (the amount of oxygen in your blood) and pulse rate *at your fingertip!* The Model 9571 is easy to use and needs no routine maintenance except battery replacement. This User Guide explains how to use and care for your ***GO$_2$ LED*** Model 9571.

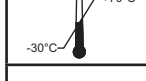
Contents of Package

- ***GO$_2$ LED*** Model 9571
- One AAA Alkaline Battery
- User Guide
- Quick Guide (Back Cover)

Symbols

*The following symbols are associated with your **GO$_2$ LED** Model 9571.*

Symbol	Definition of Symbol
	Consult Instructions for Use
	Caution!
	CE Marking: conformance to EC Directive No. 93/42/EEC for medical devices
	Type BF Applied Part (patient isolation from electrical shock).
	Not for Continuous Monitoring (no alarm for SpO_2)
	UL Mark for Canada and the United States with respect to electric shock, fire, and mechanical hazards only in accordance with IEC 60601-1, UL 60601-1 and CAN/CSA C22.2 No. 601.1.

	Battery
	Indicates separate collection for electrical and electronic equipment (WEEE).
IP33	Protected against spraying water and against access to hazardous parts with a tool, per IEC 60529.
SN	Serial Number
EC REP	Authorized Representative in the European Community
	Temperature Limitation for storage/shipping
%SpO_2	Percent Oxygen Saturation Display
	Pulse Rate Display

Intended Use

GO_2 LED Model 9571 is intended to measure blood oxygen saturation (%SpO_2) (the amount of oxygen in your blood) and pulse rate of both adults and children. It is designed for fingers (not the thumb) between 0.3 and 1.0 inch (0.8 – 2.5cm) thick. The ***GO_2 LED*** Model 9571 is intended for low perfusion conditions as defined in the specifications in this manual. Limit finger movement as much as possible when using this device. *Contact your licensed health care professional for your expected oxygen saturation level (to compare with your readings). The* ***GO_2 LED*** *Model 9571 is intended for Home Health Care Only.*

Contraindications

- Do not use the ***GO_2 LED*** in a magnetic resonance (MR) environment.

Warnings

- Keep the oximeter away from young children. Small items such as the battery door, battery, and lanyard are choking hazards.
- Certain activities may pose a risk of injury, including strangulation, if the lanyard should become wrapped around your neck. Use the lanyard with caution.

⚠*Cautions*

- Do not use the ***GO_2 LED*** as the only basis for making medical decisions. It is intended only to be used as additional information that you can give to your licensed health care professional.
- The ***GO_2 LED*** might misinterpret excessive movement as good pulse strength. Limit finger movement as much as possible when using the device.
- The ***GO_2 LED*** must be able to measure your pulse properly to give you an accurate reading. Do not put the device on the same hand/arm when using a blood pressure cuff or monitor.
- The ***GO_2 LED*** has no alarms. It will not sound if the amount of oxygen in your blood is low or if your pulse rate is too high or too low.
- Do not place the ***GO_2 LED*** in liquid or clean it with agents containing ammonium chloride, isopropyl alcohol, or products that are not listed in this User's Guide.
- The ***GO_2 LED*** is not intended for use in institutions.
- Any of the following conditions may reduce the performance of the ***GO_2 LED***:
  - flickering or very bright light;
  - weak pulse quality (low perfusion);
  - low hemoglobin;
  - arterial catheters;
  - nail polish, and/or artificial nails; and
  - any tests recently performed on you that required an injection of intravascular dyes.
- The ***GO_2 LED*** may not work if you have poor circulation. Rub your finger to increase circulation, or place the device on another finger.
- The ***GO_2 LED*** measures oxygen saturation of functional hemoglobin. High levels of dysfunctional hemoglobin (caused by sickle cell anemia, carbon monoxide, etc.) could affect the accuracy of the measurements.
- Batteries can leak or explode if used or disposed of improperly. Remove the battery if the ***GO_2 LED*** will be stored for more than 30 days.
- Do not use the ***GO_2 LED*** in a combustible environment (oxygen enriched environment).
- Do not use the ***GO_2 LED*** outside the specified operating and storage temperature ranges.
- Do not use the ***GO_2 LED*** for more than 30 minutes without relocating the device to another finger.

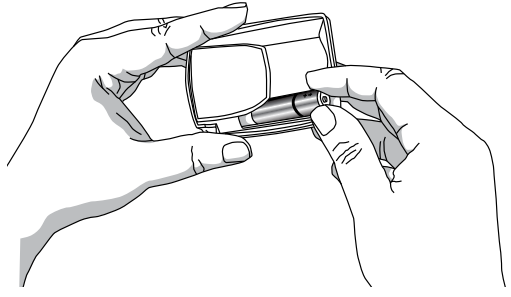
- The ***GO$_2$ LED*** needs to be used according to information provided in the User Guide.
- Do not tamper with, or hang lanyard from the flexible circuit.
- Radios and cell phones or similar devices may affect the ***GO$_2$ LED*** and should be kept at least 2 meters (7 feet) away from the device.
- Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast towers and TV broadcast towers may affect accuracy.
- Use in emergency vehicles with communication systems may affect accuracy.
- Functional tester cannot be used to assess the accuracy of this pulse oximeter.
- Follow local disposal and recycling laws for the ***GO$_2$ LED*** and its components, including the battery.
- The ***GO$_2$ LED*** is a precision electronic instrument and must be repaired by Nonin Technical Service.

Installing the Battery

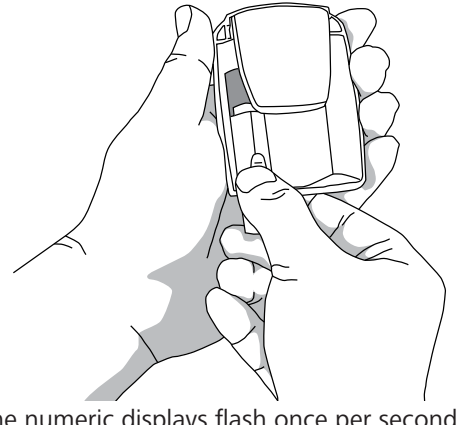
One 1.5 volt AAA-size (LR03) battery powers the ***GO$_2$ LED*** for approximately 2,400 measurements. Nonin recommends using alkaline batteries (one is included with each new ***GO$_2$ LED***). ***NOTE:*** You may use rechargeable batteries; however, they may require more frequent replacement.

1. Remove the battery door located on the left side of the ***GO$_2$ LED*** by sliding it towards you (see page 9 diagram).

2. Insert one new 1.5 volt AAA-size battery. Follow the plus (+) and minus (-) markings for battery direction (as shown inside of the battery compartment).



3. Carefully reposition the battery door. ***NOTE:*** Do not force it into place; it fits only when positioned correctly.



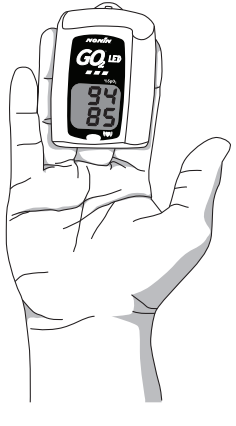
When battery is low, the numeric displays flash once per second. Replace battery as soon as possible. Remove battery if the device will be stored for more than 30 days.

Applying the *GO$_2$ LED* Model 9571 to Your Finger

Hold the ***GO$_2$ LED*** with the display facing toward you; slide your finger into the opening at the bottom of the device, as shown below, until the fingertip touches the built-in stop guide.

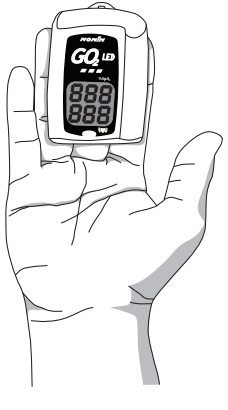
For best results, make sure the finger is centered within the finger guide; keep the ***GO$_2$ LED*** at heart or chest level.

NOTE: Correct positioning of the device on your finger is critical for accurate measurements. While on the finger, do not press the ***GO_2 LED*** against any surface and do not squeeze or hold it together. The internal spring provides the correct pressure; additional pressure may cause inaccurate readings.



Activating the Device and Verifying Operation

The ***GO_2 LED*** automatically turns on when a finger is inserted. When a finger is inserted, the ***GO_2 LED*** performs a brief self test, as shown below. Verify that all segments of the LED (Light Emitting Diode) display appear during the startup sequence.



Reading Your Results

When you put your finger in the ***GO$_2$ LED***, you'll notice an LED display come on. The numbers you see show:

- the amount of oxygen in your blood, displayed as %SpO_2; and
- your Pulse Rate, displayed as a 2 or 3 digit number, measuring the number of times your heart beats per minute.

At the bottom of the display window, a tricolor LED Pulse Quality Indicator shows the pulse signal quality, while blinking at the corresponding pulse rate. This display changes colors to alert you to changes in pulse quality that may affect the readings: *green* - good pulse signal, *yellow* - marginal pulse signal, and *red* - an inadequate pulse signal.

If you are not getting a pulse rate reading and your pulse quality indicator is marginal or inadequate, warm the finger or reposition to another finger.

After the startup sequence, the ***GO$_2$ LED*** begins sensing the pulse (indicated by the blinking pulse quality indicator). Allow the device to stabilize, observing about 4 seconds of continuous green-colored pulse quality before relying on the displayed values. It is common for the displayed values to fluctuate slightly over a period of several seconds. If the pulse quality indicator blinks yellow or red, try another finger.

A minus sign (-) appears in the left-most digit of the %SpO_2 display when the ***GO$_2$ LED*** senses that the finger has been removed. The last measured SpO_2 and pulse rate values freeze for 10 seconds, then the device turns off. The device will automatically shut off (to conserve battery life) approximately 10 seconds after the finger is removed, or after a 2-minute period of inadequate pulse signals.

Care and Maintenance

The ***GO$_2$ LED*** requires no calibration or periodic maintenance other than battery replacement. Wipe the device with a soft cloth dampened with a mild detergent or 10% bleach solution. Do not use undiluted bleach or any cleaning solution other than those recommended here, as permanent damage could result. Dry with a soft cloth, or allow to air dry. Clean once per week or more frequently if handled by multiple users.

⚠ ***Caution:*** Do not place the ***GO$_2$ LED*** in liquid or clean it with agents containing ammonium chloride, isopropyl alcohol, or products that are not listed in this User's Guide.

Troubleshooting

Problems	Possible Cause	Possible Solutions
Display Lockup	Display does not appear to change (you should see the pulse quality indicator flash green or yellow if the device is on the finger).	***Reposition** finger or change fingers.* ***Remove** and replace battery.* *If the problem persists **contact** Nonin Technical Service.*

Troubleshooting

Problems	Possible Cause	Possible Solutions
Display blank	Nothing appears on the display.	***Reposition*** *finger to activate the device.* ***Verify*** *battery is correctly inserted.* ***Note:*** *If battery is installed backwards, the unit will not function.* *Dead battery. Replace battery.* *May be too cold. Allow device to sit at room temperature for at least 30 minutes.* *After unit has been dropped or shocked, battery may need to be removed and reinstalled.* *If the problem persists* ***contact*** *Nonin Technical Service.*

Troubleshooting

Problems	Possible Cause	Possible Solutions
Missing segments on LED display.	Faulty display.	***Contact*** *Nonin Technical Service.*
No readings	Low pulse quality (no reading).	*Try the following:* *1. Reposition finger.* *2. Warm finger by rubbing.* *3. Select a different finger.* *For more information, please see Reading Your Results.*

Parts and Accessories

GO2CC *Black neoprene carrying case with belt loop*

GO2L *Black 20" lanyard*

GO2R *Clip on retractable holder*

WARNING: Certain activities may pose a risk of injury, including strangulation, if the lanyard should become wrapped around your neck. Use the lanyard with caution.

For more information about Nonin parts and accessories, contact your distributor, or contact Nonin at (877) 577-2635 (USA and Canada) or (763) 553-9968.

Specifications

Oxygen Saturation Display Range	0% to 100%
Pulse Rate Display Range	18 to 321 beats per minute (BPM)
Oxygen Saturation Declared Accuracy Range (A_{rms}*)	70% to 100% SpO_2 ± 2 digits
Low Perfusion Oxygen Saturation Declared Accuracy Range (A_{rms}*)	70% to 100% SpO_2 ± 2 digits
Pulse Rate Declared Accuracy Range(A_{rms}*)	20 to 250 BPM ± 3 digits
Low Perfusion Pulse Rate Declared Accuracy Range (A_{rms}*)	40 to 240 BPM ± 3 digits
Measurement Wavelengths and Output Power	
Red	660 nanometers @ 0.8mW Max Average
Infrared	910 nanometers @ 1.2mW Max Average

*± 1 A_{rms} represents approximately 68% of measurements.

Temperature (Operating)	+41°F to +104°F (5°C to +40°C)
Storage/Transportation	-22°F to +158°F (-30°C to +70°C)

Device temperature will not exceed 41°C as measured during a controlled environment test.

Humidity (Operating)	10% to 90% relative humidity, non-condensing
Storage/Transportation	10% to 95% relative humidity, non-condensing
Operating Altitude	Up to 40,000 feet /12,192 meters
Battery Life (Continuous)	Approximately 2400 spot checks based on ~21 hours of operation using one AAA-size alkaline battery, calculated at 30 seconds per use.
Battery Life (Storage)	6 months minimum

Classifications per IEC 60601-1 / CAN/CSA-C22.2 No. 601.1 / UL 60601-1

Degree of Protection	Type BF-Applied Part
Enclosure Degree of Ingress Protection	IP33
Mode of Operation	Continuous

This equipment complies with International Standard IEC 60601-1-2:2004 for electromagnetic compatibility for medical electrical equipment and/or systems. This standard is designed to provide reasonable protection against harmful interference in a typical installation. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in health care, home, and many other environments, it is possible that high levels of such interference due to close proximity or strength of a source might disrupt the performance of this device.

This product complies with ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing.

Equipment Response Time

Specific to this example: The response of the 4-beat average is 1.5 seconds.

Testing Summary

SpO_2 accuracy and low perfusion testing were conducted by Nonin Medical, Inc., as described below:

SpO_2 Accuracy Testing

SpO_2 accuracy testing is conducted during induced hypoxia studies on healthy, non-smoking, light- to dark-skinned subjects during motion and no-motion conditions in an independent research laboratory. The measured arterial hemoglobin saturation value (SpO_2) of the sensors is compared to arterial hemoglobin oxygen (SaO_2) value, determined from blood samples with a laboratory co-oximeter. The accuracy of the sensors in comparison to the co-oximeter samples measured over the SpO_2 range of 70 - 100%. Accuracy data is calculated using the root-mean-squared (Arms value) for all subjects, per ISO 9919:2005, Medical Electrical Equipment–Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.

Pulse Rate Motion Testing

This test measures pulse rate oximeter accuracy with motion artifact simulation introduced by a pulse oximeter tester. This test determines whether the oximeter meets the criteria of ISO 9919:2005 for pulse rate during simulated movement, tremor, and spike motions.

Low Perfusion Testing

This test uses a SpO_2 Simulator to provide a simulated pulse rate, with adjustable amplitude settings at various SpO_2 levels for the oximeter to read. The oximeter must maintain accuracy in accordance with ISO 9919:2005 for heart rate and SpO_2 at the lowest obtainable pulse amplitude (0.3% modulation).

Warranty

Nonin warrants to the purchaser, for 2 years from the date of purchase, each ***GO_2 LED-*** Model 9571 exclusive of the battery. Nonin will repair or replace any ***GO_2 LED*** Model 9571 found to be defective in accordance with this warranty, free of charge, for which Nonin has been notified by the purchaser by serial number that there is a defect, provided notification occurs within the applicable warranty period.

This warranty excludes cost of delivery to and from Nonin. Nonin reserves the right to charge a fee for a warranty repair request on any ***GO_2 LED*** Model 9571 found to be within specifications. ***GO_2 LED*** Model 9571 is a precision electronic instrument and must be repaired by Nonin Technical Service. Any sign or evidence of opening the ***GO_2 LED*** Model 9571, field service by non-Nonin personnel, tampering, or any kind of misuse of the ***GO_2 LED*** Model 9571, shall void the warranty. The ***GO_2 LED*** Model 9571 is warranted for Home Health Care Use Only. All non-warranty work shall be done at Nonin's standard rates and charges in effect at the time of delivery to Nonin.

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EC REP

Authorized EC Representative:
MPS, Medical Product Service GmbH
Borngasse 20
D-35619 Braunfels, Germany

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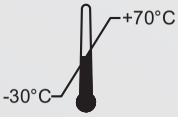
7366-201-01

Please take a moment to find and record the 9-digit serial number found on the back of your ***GO$_2$ LED*** Model 9571. You'll need this number if you have to contact Nonin with technical service issues or if you have any questions regarding the use or performance of your pulse oximeter. Nonin's technical service department can be reached at (877) 577-2635.

My Serial Number: _____



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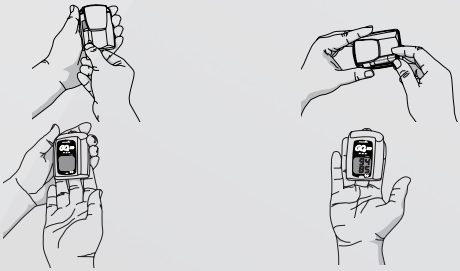

Warning: *Keep away from small children; this device contains small parts that may pose a choking hazard.*